United States Court of Appeals
FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued March 17, 1995 Decided August 25, 1995

No. 94-5041

A.L. PHARMA, INC.,
APPELLANT

v.

DONNA E. SHALALA, ET AL.,
APPELLEES

Appeal from the United States District Court
for the District of Columbia

(83cv01603)

James H. Wallace Jr., with whom *James M. Johnstone* and *Richard L. McConnell Jr.* were on the briefs, argued the cause for appellant.

Jeffrey B. Chasnow, Attorney, United States Department of Justice, with whom *Frank W. Hunger,* Assistant Attorney General, and *Catherine L. Copp,* Associate Chief Counsel, Food and Drug Administration, were on the brief, argued the cause for appellees.

Before EDWARDS, *Chief Judge,* and BUCKLEY and GINSBURG, *Circuit Judges.*

Opinion for the court filed by *Circuit Judge* BUCKLEY.

BUCKLEY, *Circuit Judge*: To gain Food and Drug Administration approval for the sale of a new animal drug, an applicant must demonstrate that it is both safe and effective for its intended uses. Finding that this standard had been met, the FDA approved for sale a drug produced by Philips Roxane, Inc., which is marketed to improve growth and feed efficiency in broiler chickens. Appellant A.L. Pharma, Inc. ("A.L."), a competitor of Philips Roxane, petitioned the FDA to reverse its approval and, receiving no satisfaction from the agency, sought relief in the district court. The district court granted summary judgment for the agency, and A.L. appeals. We affirm in part and reverse and remand in part with instructions to the district court to return the matter to the FDA for a more reasoned justification of its actions.

I. BACKGROUND

A. New Animal Drug Application No. 128-550

The tortured story of this litigation begins in 1981, when Philips Roxane first sought FDA permission to sell two chicken feed mixes containing bacitracin zinc, a drug used to increase the rate of growth and feed efficiency in poultry. The Food, Drug and Cosmetic Act ("FDCA") provides that any new animal drug is considered unsafe prior to receiving FDA approval for its intended use. 21 U.S.C. § 360b(a)(1)(A) (1988). To secure such approval, the FDCA requires the applicant to file a New Animal Drug Application ("NADA") that includes information demonstrating both the safety and the efficacy of the drug. *Id.* § 360b(d)(1)(A), (B) & (E) (1988). Philips Roxane's bacitracin zinc feed mixes are regulated by these provisions, and the company accordingly filed New Animal Drug Application No. 128-550 ("NADA 128-550") in order to obtain FDA approval to market the products.

In the early 1970's, the Animal Health Institute ("AHI"), an industry trade association, coordinated a safety study on bacitracin zinc, the results of which were to be shared by the pharmaceutical companies that contributed to the research costs. *See A.L. Labs., Inc. v. Philips Roxane, Inc.,* 803 F.2d 378, 380 (8th Cir. 1986). In 1973, copies of the study were sent to the FDA and placed in what the agency calls its "master files" for subsequent use by the study's sponsors. When Philips Roxane submitted its application, it referred to one of these master files, MF 3578, as evidence that its product met the FDA's safety requirement. *See A.L. Labs.,* 803 F.2d at 380. There is no dispute that the AHI study provided an adequate basis for the FDA to determine that Philips Roxane's product was "safe for use under the conditions prescribed, recommended, or suggested in the proposed labeling," as required by the FDCA. 21 U.S.C. § 360b(d)(1)(A).

That study, however, did not establish that Philips Roxane's product met the agency's efficacy requirement. The FDCA conditions the FDA's approval of a NADA on

> substantial evidence that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof....

21 U.S.C. § 360b(d)(1)(E). It defines "substantial evidence" to mean

> evidence consisting of adequate and well-controlled investigations, including field investigation, by experts qualified by scientific training and experience to evaluate the

> effectiveness of the drug involved, on the basis of which it could fairly and reasonably be concluded by such experts that the drug will have the effect it purports or is represented to have under the conditions of use prescribed, recommended, or suggested in the labeling or proposed labeling thereof.

21 U.S.C. § 360b(d)(3) (1988). To paraphrase, then, a NADA generally must include evidence that the applicant's drug is not only safe, but that it will do what the applicant claims it will do. The FDA's regulations mirror the statute, requiring manufacturers to provide "substantial evidence" of the "effectiveness of the drug involved...." 21 C.F.R. § 514.111(a)(5)(i) (1994).

In 1970, the National Academy of Sciences/National Research Council conducted a study of the efficacy of bacitracin zinc drugs. 35 Fed. Reg. 11,531 (1970). Based on the Academy's findings concerning the effectiveness of bacitracin zinc products used to increase the rate of growth and feed efficiency in poultry, the FDA concluded that the drug "c[ould] be moved into the effective category"; it also provided, by regulation, that it would approve applications for bacitracin zinc drugs "identical" to the one tested by the Academy if, in lieu of direct proof of effectiveness, the applicant submits "bioequivalency or similar data ... as suggested in the guideline for submitting NADA's for generic drugs reviewed by the [Academy]." 46 Fed. Reg. 37,043, 37,044 (1981) (codified at 21 C.F.R. § 558.78 (1994)). This regulation provided Philips Roxane with an important shortcut to FDA approval. Instead of conducting studies to prove that its particular product actually would promote growth and feed efficiency in chickens, Philips Roxane had the option of demonstrating that its product was "bioequivalent" to the "benchmark" product that the Academy had found to be effective for those purposes.

This regulatory shortcut, of course, begs the question of what precisely a manufacturer must prove for the FDA to deem its product "bioequivalent" and therefore effective. Unfortunately, neither the regulation nor the guideline referred to in the Federal Register sheds any light on the matter. The guideline merely instructs the applicant to submit "bioequivalency data which compares and establishes the similarity of the generic drug to that reviewed by the Academy preferably in the target animal."

To establish bioequivalency, Philips Roxane commissioned Dr. John Prescott of the University of Guelph in Ontario, Canada, to conduct a study comparing its bacitracin zinc product with that of

the benchmark product manufactured by International Minerals & Chemical Corp. ("International Minerals"). To this end, Dr. Prescott tested the ability of the Philips Roxane and International Minerals products to prevent the experimental inducement of a disease organism, necrotic enteritis, in a population of chickens, and found the two equally effective for that purpose.

In 1982, the FDA issued a rule approving NADA 128-550, based on its conclusion that Philips Roxane's bacitracin zinc product was safe and effective for increasing the rate of weight gain and improving feed efficiency in chickens. 47 Fed. Reg. 35,187 (1982). The agency noted that the Philips Roxane and International Minerals feed mixes were similar and determined that the Prescott necrotic enteritis study "establishes bioequivalency" between the two. *Id.*

B. A.L. Pharma's Challenge

Over the past thirteen years, A.L. has filed no fewer than four citizen petitions with the FDA, *see* 21 C.F.R. § 10.25(a), 10.30 (1994), requesting the withdrawal of the rule approving Philip Roxane's application, each of which the agency has rejected. After the FDA's denial of A.L.'s first citizen petition, A.L. brought suit in the U.S. District Court for the District of Columbia seeking a declaration that the approval of Philip Roxane's application was unlawful and an injunction setting it aside. That suit was amended on subsequent occasions to incorporate the agency's denial of subsequent citizen petitions. Although A.L. has challenged the approval of the application on a number of grounds, it presses only two on appeal.

The first of these has its roots in an allegation in A.L.'s initial citizen petition that it, not Philips Roxane, owned the safety data in MF 3578 and that the FDA's reliance on it was therefore improper. The FDA responded that its records indicated that Philips Roxane owned the MF 3578 data and that any dispute over the ownership of that information was "more appropriately resolved" in a civil suit for misappropriation of trade secrets that A.L. was then pursuing against Philips Roxane in the U.S. District Court for the Western District of Missouri than in an administrative proceeding. Letter from Joseph P. Hile, FDA Assoc. Commissioner for Regulatory Affairs, to James J. Johnstone, Esq., and Bruce L. McDonald, Esq., Attorneys for A.L. Pharma ("1982 Petition Denial"), *reprinted in* Joint Appendix ("J.A.") at 137.

A.L. eventually prevailed in that lawsuit. On appeal, the Eighth Circuit upheld an award of $785,000 in punitive damages and a 51-month injunction against Philips Roxane's sale of bacitracin zinc to compensate for the time it would have taken the company to replicate the safety data and then secure FDA approval based on those independent results. *A.L. Labs.*, 803 F.2d at 383-85. With this judgment in hand, A.L. returned to the FDA seeking rescission of its approval of Philips Roxane's application. By this time, however, the application no longer relied on MF 3578. Philips Roxane had since purchased from another sponsor of the AHI study the right to refer to its copy of the safety data and had amended its application to refer to that alternative file. The FDA ruled that revoking its approval would serve no public health purpose and that neither the FDCA nor the citizen petition rules contemplated the use of the FDA's administrative procedures for punitive action against an animal drug manufacturer.

Second, A.L. maintains that the Prescott Study did not establish the bioequivalency of the Philips Roxane bacitracin zinc and the International Minerals benchmark product. In support of its initial citizen petition, the company submitted affidavits and letters of sixteen highly credentialed scientists, all of whom questioned the bioequivalency conclusion. The agency responded that the Prescott Study's demonstration that the two drugs' biological activity against the necrotic enteritis disease organism were not significantly different, "together with manufacturing data and the results of microbiological assays, adequately establish that drugs from the two sources will be equally effective for increased weight gain and improved feed efficiency." 1982 Petition Denial at 2.

A.L. argued, in the district court, that the FDA acted arbitrarily in denying its petitions because the agency misapplied its "bioequivalency" standard and, in any event, that it violated its regulations when it declined to withdraw its approval of the application upon learning that Philips Roxane had falsely claimed that it owned the safety data. In December 1993, the district court granted the agency's motion for summary judgment. *A.L. Labs. v. Shalala,* No. Civ. A. 83-1603 (D.D.C. Dec. 21, 1993) ("*Memorandum Opinion*"). The court held that the FDA properly permitted Philips Roxane to substitute the untainted safety data for the identical data owned by A.L., and that there was nothing in the agency's rules that obliged it to withdraw approval of the application based

on the ownership dispute. *Id.* at 12-13. The court also deferred to the agency's bioequivalency judgment, noting that the record indicated that the "FDA evaluated alternative means of establishing bioequivalence" before approving the Prescott Study and deciding that "this Court is not in a position to decide which scientific method is preferable." *Id.* at 11. A.L. then filed this appeal.

II. DISCUSSION

A. The Safety Data

A.L. contends that the FDA failed to follow its own regulations when it refused to rescind the application as a consequence of Philips Roxane's misrepresentation of its ownership of the safety data. A.L. relies on an FDA regulation that provides:

> Any reference to information furnished by a person other than the applicant may not be considered unless its use is authorized in a written statement signed by the person who submitted it.

21 C.F.R. § 514.1(a) (1994).

Pointing to its successful misappropriation suit in the Eighth Circuit, A.L. argues that the FDA never should have permitted Philips Roxane to rely on the safety data in MF 3578 and that it violated its regulation by so doing. The remedy, A.L. urges, is rescission of the FDA's approval of the NADA, thus requiring Philips Roxane to file a new application and shepherd it through another approval process.

The initial problem with A.L.'s theory is that it incorrectly presumes that establishing its ownership rights in MF 3578, which it did in its civil suit, constitutes proof that the FDA failed to abide by its regulation. By its terms, the regulation prevents the agency from using data submitted by one party for the benefit of another without the permission of the submitter. It thus provides pioneering animal drug manufacturers with a reasonable expectation that their research and development investments will not inure to the benefit of their competitors. *See Tri-Bio Labs., Inc. v. United States,* 836 F.2d 135, 140-41 (3d Cir. 1987). The regulation does not, however, require or even invite the FDA to adjudicate ownership disputes between competitors, as A.L. seems to suggest.

The evidence presented to the district court clearly indicates that the FDA did not violate the

terms of section 514.1(a). In its motion for summary judgment, the FDA alleged, and A.L. did not dispute, that the safety data was submitted to the FDA by AHI along with a list of the study's sponsors, which included Philips Roxane. In other words, "the person who submitted" the data to the FDA "authorized" Philips Roxane's use. 21 C.F.R. § 514.1(a). Consequently, there was "no genuine issue as to any material fact," Fed. R. Civ. P. 56(c); and the agency was entitled to summary judgment on that claim. Whether AHI erred by including Philips Roxane on the list of study sponsors or, as A.L. argued to the district court, Philips Roxane had an obligation arising from an understanding with an A.L. affiliate not to make use of the data, are issues that are simply not relevant to the question of whether the FDA failed to abide by its regulation.

Even if the agency had violated its regulation when it approved Philip Roxane's application, A.L.'s proposed remedy of vacatur and remand would be inappropriate in light of Philips Roxane's replacement of the reference to MF 3578 in its application with a reference to the identical data in a different master file. A.L. attempts to analogize this case to instances in which we have found an agency action invalid due to procedural error and ordered the agency to repeat its process in accordance with law. The cases it cites are distinguishable, however, by virtue of the fact that the agencies involved had failed to take any corrective action. *See, e.g., American Cyanamid Co. v. FDA,* 606 F.2d 1307, 1323-24 (D.C. Cir. 1979) (reversing FDA order when agency failed to grant appellant a statutorily mandated hearing); *Panhandle Eastern Pipe Line Co. v. FERC,* 613 F.2d 1120, 1134-36 (D.C. Cir. 1979) (setting aside FERC order when agency misinterpreted its regulations); *Way of Life Television Network, Inc. v. FCC,* 593 F.2d 1356, 1358-59 (D.C. Cir. 1979) (reversing FCC licensing decision when agency improperly failed to publish a required notice in the Federal Register).

Because the FDA has now approved Philips Roxane's product on the basis of unquestionably proper safety data, it is clear that were we to vacate the FDA's approval of the application and remand, Philips Roxane would merely duplicate its amended NADA, which refers to the data in the replacement master file, and the FDA would approve the application. We do not remand where "[t]here is not the slightest uncertainty as to the outcome of a[n] [agency] proceeding...." *NLRB v.*

Wyman-Gordon Co., 394 U.S. 759, 766-67 n.6 (1969); *see also American Train Dispatchers Ass'n v. ICC,* 26 F.3d 1157, 1163 (D.C. Cir. 1994) ("A remand is unnecessary where, as here, the outcome of a new administrative proceeding is preordained.").

A remand of the FDA's action in this circumstance would serve only one purpose: the punishment of Philips Roxane. To the extent that a misstatement in Philips Roxane's application harmed A.L. directly, the latter's proper recourse was in the civil suit that it has, in fact, prosecuted and won. To the extent that the misrepresentation harmed the FDA's administrative process, the agency has broad latitude to determine an appropriate response. It is well within the discretion of the FDA to decide not to penalize the company by withdrawing its approval of NADA 128-550. *See ABF Freight System, Inc. v. NLRB,* 114 S. Ct. 835, 839-40 (1994) (finding no abuse of discretion when the NLRB relied on "other civil and criminal remedies" to punish victim of an unfair labor practice for lying to the Board rather than denying him administrative relief).

B. Bioequivalency

A.L. also renews its challenge to the agency's finding of bioequivalency between Philips Roxane's bacitracin zinc and the benchmark product. It relies on affidavits and letters of sixteen veterinary medicine research scientists that it submitted to the FDA to support its initial citizen petition. Each of these experts contended that the results of the Prescott Study do not establish bioequivalency. A.L. maintains that the unanimous views of these experts conclusively establish that the FDA acted arbitrarily and thus illegally when it refused to rescind its approval of the NADA.

The scientists advance two formidable criticisms of the Prescott Study and of its acceptance by the FDA as proof of bioequivalency. First, a number of them contend that a test of the relative effectiveness of two drugs for the purpose of fighting a disease cannot prove equivalent effectiveness for the purpose of promoting growth and feed efficiency. Second, A.L.'s experts questioned whether the Prescott Study proved even that the drugs were equivalent for the purpose of fighting necrotic enteritis, because the two drugs were tested at a single dosage. To reach such a conclusion, they argue, different dosages would have to be tested and dose-response curves for the two products constructed and compared. Without dose-response curves constructed from multiple data points,

they believe, there is no way to rule out the possibility that one of the drugs barely reached effectiveness at the dosage tested while the other would have been effective against the disease at a fraction of the dose.

In denying A.L.'s first citizen petition, the FDA defended its reliance on Prescott's disease study to establish bioequivalence by pointing out that because it is not possible to measure bacitracin zinc levels in blood, this commonly used method for establishing bioequivalency was not available. In addition, it noted it "d[id] not believe that it [was] necessary to test different levels of the drugs and compare dose- response curves" in order to show "that the biological activity of the two drugs against a known disease organism was not significantly different." 1982 Petition Denial at 2. On appeal, the agency maintains that its scientific determinations were supported by the administrative record. It specifically refers to its internal scientific evaluations and an affidavit provided by Dr. Prescott stating his belief that, given certain assumptions, the two drugs "could be presumed to be bioequivalent in clinical use...." Affidavit of John Prescott, Dec. 10, 1982, *reprinted in* J.A. at 106-07.

As the FDA stresses, courts give a high level of deference to an agency's evaluations of scientific data within its area of expertise. *See, e.g., Schering Corp. v. FDA,* 51 F.3d 390, 399 (3d Cir. 1995) (FDA's "judgments as to what is required to ascertain the safety and efficacy of drugs falls squarely within the ambit of the FDA's expertise and merit deference from us."); *International Fabricare Inst. v. EPA,* 972 F.2d 384, 389 (D.C. Cir. 1992) (rationale for deference "particularly strong" when agency evaluates scientific evidence within its technical expertise). In addition, we must defer to an agency's interpretation of its own regulations "unless it is plainly erroneous or inconsistent with the regulation," *K N Energy, Inc. v. FERC,* 968 F.2d 1295, 1299 (D.C. Cir. 1992) (quoting *United States v. Larionoff,* 431 U.S. 864, 872 (1977)), regardless of whether interpreting the regulation requires an agency's technical expertise. As an FDA regulation not challenged here permits Philips Roxane to prove effectiveness by establishing bioequivalency but does not explicitly define that term, 46 Fed. Reg. 37,043, 37,044, the agency has broad latitude in interpreting the standard.

Deferring to an agency's exercise of its discretion, however, is not tantamount to abdicating

the judiciary's responsibility under the Administrative Procedure Act to set aside agency actions that are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A) (1994). To enable us to fulfill our duty, "an agency must cogently explain why it has exercised its discretion in a given manner," *Motor Vehicle Mfr's Ass'n of the United States, Inc. v. State Farm Mut. Auto. Ins. Co.,* 463 U.S. 29, 48 (1983); and that explanation must be "sufficient to enable us to conclude that the [agency's action] was the product of reasoned decisionmaking." *Id.* at 52. Based on the record before us, we are unable to say that it was.

Of the two principal arguments advanced in A.L.'s affidavits as to why the study could not prove bioequivalency, we are able to discern a reasoned response to only one. As the FDA explained, because it had already determined that Philips Roxane's bacitracin zinc was "identical" to that in the benchmark drug, the company was entitled to substitute proof of bioequivalency for proof of effectiveness. *See* 46 Fed. Reg. at 37,044 (establishing rule that "approval for identical products in poultry need not include certain types of efficacy data" normally required); 1982 Petition Denial at 1 (Philips Roxane and benchmark products "are considered "identical' "). Therefore, the purpose of the Prescott Study was not to prove the effectiveness of Philips Roxane's products but, rather, to determine whether they were bioequivalent with the benchmark drug. *See* 1982 Petition Denial at 2.

As we understand it, the FDA requires companies like Philips Roxane to submit bioequivalency data not to determine whether the new drug contains the ingredients necessary to promote growth and improve feed efficiency, because that has already been established; instead, it seeks to determine whether the drug's delivery mechanism operates similarly to that of the benchmark product. In this case, the FDA's scientists believed that "the expected differences [between the performance of drugs in the necrotic enteritis study] ... are much greater than those for growth experiments," Memorandum of Thomas V. Raines, D.V.M., Aug. 25, 1981, *reprinted in* J.A. at 37; thus, a comparison of the drugs' abilities to fight disease was perhaps even a better measure of the similarities of their delivery mechanisms than a direct comparison of the drugs' effects on growth promotion. This position reflects a scientific determination within the scope of the FDA's expertise,

to which we defer.

The agency, however, has provided no similarly reasoned explanation of why it disagrees with A.L.'s experts' criticism that a single-dosage test cannot prove bioequivalency. Those scientists charged, in effect, that the two drugs could have had an identical effect on necrotic enteritis during the Prescott Study even if one delivered twice as much of the active ingredient or delivered it twice as rapidly. Whether this criticism is relevant depends on what characteristics the two drugs must share in order to be deemed bioequivalent. The FDA correctly defines the term "bioequivalence" in the human drug context to mean

> the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same molar dose under similar conditions in an appropriately designed study.

21 C.F.R. § 320.1(e) (1994); *compare* 21 U.S.C. § 355(j)(7)(B) (1988) (similar definition in human drug portion of FDCA). The agency has not defined the term, by regulation, in the animal drug context.

It is doubtful that the Prescott Study could meet the human drug bioequivalency standard because, as A.L.'s experts note, comparisons of the rate and extent to which two drugs are delivered to the site of drug action cannot be drawn from evaluations of the effects of a single dosage, at least when it is not possible to measure the level of the drug in the bloodstream over time. There may be more than one reasonable definition of bioequivalency, however; and the agency is entitled to latitude in its construction of the term. But on the evidence before us, we cannot say that the FDA has provided an adequate explanation for its conclusion that the Prescott Study demonstrated the bioequivalency of the Philips Roxane and International Minerals bacitracin zinc products.

The FDA has made no attempt to "cogently explain," *State Farm,* 463 U.S. at 48, why A.L. is mistaken when it contends that a single-dosage study unaccompanied by blood level comparisons cannot prove bioequivalency. Neither its conclusory response to A.L. that it "does not believe that it is necessary to test different levels of the drugs and compare dose-response curves," 1982 Petition Denial at 2, nor its reminders that its scientific determinations are entitled to deference are sufficient to enable us to reach the independent conclusion that its decision was the "product of reasoned

decisionmaking." *State Farm,* 463 U.S. at 52. Accordingly, the district court erred by granting the FDA's motion for summary judgment. We remand the issue so that the FDA may explain what bioequivalency entails in the animal drug context and how the Prescott Study satisfied that standard.

Although, on this record, we are unable to conclude that the FDA's approval of Philips Roxane's application was not arbitrary and capricious, we are not required to vacate the approval. *See Checkosky v. SEC,* 23 F.3d 452, 462-66 & App. (D.C. Cir. 1994) (Silberman, J.) (failure to provide satisfactory explanation does not necessarily mean that agency has acted illegally; therefore, court has discretion not to vacate agency action pending agency's elaboration of its reasoning); *Allied-Signal, Inc. v. NRC,* 988 F.2d 146, 151 (D.C. Cir. 1993) (remanding rule to agency without vacating "to develop a reasoned" explanation for its action). In deciding whether to vacate an agency's decision pending further explanation, we consider "the seriousness of the order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed." *International Union, United Mine Workers of Am. v. Federal Mine Safety and Health Admin.,* 920 F.2d 960, 967 (D.C. Cir. 1990).

In this case, the FDA may well be able to explain why it reasonably determined that the Prescott Study demonstrated bioequivalency. In addition, vacating the rule approving the NADA would prove disruptive to Philips Roxane, which has relied on it in good faith for over thirteen years. By the same token, nothing in the record suggests that significant harm would result from allowing the approval to remain in effect pending the agency's further explanation. *Cf. Maryland People's Counsel v. FERC,* 768 F.2d 450, 455 (D.C. Cir. 1985) (declining to vacate agency order due to expire soon where impact on petitioners and others similarly situated "is not likely to be especially severe"). Therefore, we will leave the rule in place for a period of 90 days following the issuance of this opinion. If, by the end of that period, the FDA has failed to provide an adequate justification for its conclusion that the two drugs are bioequivalent, the rule approving Philips Roxane's application will be vacated automatically as of the end of the 90th day.

III. CONCLUSION

For the reasons stated above, we set aside the district court's grant of summary judgment for

the FDA and remand the case to the court with instructions to return the matter of NADA 128-550 to the FDA for either reconsideration or an adequate explanation of its determination that the Prescott Study established bioequivalency.

So ordered.